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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHUANG LIU, JOHN A. BARRETT
and ALAN P. CARPENTER, JR.

Appeal 2010-011420
Application 09/899,629
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This appeal under 35 U.S.C. § 134 involves claims 19-22, 30-33, and 35-39.² We have jurisdiction under 35 U.S.C. § 6(b).

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

² Pending claims 1-18, 23-29, 34, and 40-92 were withdrawn from consideration (App. Br. 2).

STATEMENT OF THE CASE

The claims are directed to a pharmaceutical composition. Claim 19 is representative and is reproduced in the “Claims Appendix” of Appellants’ Brief (App. Br. 28).

The rejections presented by the Examiner follow:

1. Claims 19-22, 30, 31, 33, and 35-39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Sworin,³ Vanderheyden,⁴ and Yoshinaga.⁵
2. Claims 19-22, 30-33, and 35-39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Toner,⁶ Vanderheyden, and Yoshinaga.
3. Claims 19-22, 30-33, and 35-39 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22 and 28-30 of Rajopadhye⁷ in view of Vanderheyden and Yoshinaga.

We affirm.

Obviousness:

Appellants’ arguments for each rejection under 35 U.S.C. § 103(a) are essentially the same. Accordingly, we address them together. In addition, while Appellants separately identify the requirements of each dependent

³ Sworin et al., US 5,750,088, issued May 12, 1998.

⁴ Vanderheyden et al., US 5,679,318, issued October 21, 1997.

⁵ Yoshinaga, JP 56-144060, published November 10, 1981, as translated PTO: 200-5-2710.

⁶ Toner et al., US 5,707,603, issued January 13, 1998.

⁷ Rajopadhye et al., US 6,537,520 B1, issued March 25, 2003.

claim on appeal, Appellants contend that for each dependent claim on appeal “[t]he Examiner has failed to make a proper *prima facie* showing for these claims for the reasons above” regarding independent claim 19 (App. Br. 16-20 and 23-27). We do not find Appellants’ separate listing of the dependent claims on appeal to represent a separate argument of these claims. Accordingly, the dependent claims included in each ground of rejection will stand or fall together with independent claim 19.

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

FINDINGS OF FACT

- FF 1. Appellants do not dispute the Examiner’s finding that Sworin and Toner suggest a radiolabeled pharmaceutical agent within the scope of Appellants’ formula (II) (*see* Ans. 8-9 and 10; *Cf.* App. Br. 14-15 and 21).
- FF 2. The Examiner finds that Sworin and Toner fail to teach the addition of a stabilizer, such as gallic acid, to a radionuclide conjugate composition (App. Br. 9 and 10 respectively).
- FF 3. The Examiner finds that Vanderheyden suggests that therapeutic radionuclide compositions generally require a stabilizer, i.e. an antioxidant, such as “gentisic acid, or its derivatives, or functionally similar compounds . . . suitable for in vivo human administration” (Ans. 9 and 11).
- FF 4. The Examiner finds that Yoshinaga suggests that gallic acid (3, 4, 5 trihydroxy benzoic acid) is an antioxidant that is suitable for human consumption (*id.*).
- FF 5. Yoshinaga suggests that the antioxidant properties of gallic acid are multiplied when it is mixed with ascorbic acid (Yoshinaga 2: 7-9).

FF 6. The Examiner finds that Vanderheyden teaches “a specific dihydroxy benzoic acid [gestisic acid], and its derivatives or functionally similar compounds, for use as antioxidants” and that this teaching “would have fairly suggested that [Yoshinaga’s] trihydroxy benzoic acid would be similarly useful” (Ans. 15 and 16).

ANALYSIS

Appellants contend that Formula I of their claim 19 excludes the three antioxidants suggested by Vanderheyden, specifically ascorbic acid, gentisic acid, and reductic acid (App. Br. 15). We are not persuaded. The Examiner relies on Vanderheyden to suggest that therapeutic radionuclide compositions generally require the presence of a stabilizer (FF 3).

The Examiner relies on Yoshinaga to suggest an antioxidant stabilizer that is suitable for human consumption (FF 4). There is no evidence on this record to support a conclusion that Yoshinaga’s stabilizer is not within the scope of Appellants’ formula I. Further, as to Appellants’ contention that Yoshinaga is non-analogous art, we note that “[a] reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d 656, 659 (Fed.Cir.1992). In this regard, notwithstanding Appellants’ contention to the contrary, Yoshinaga suggests gallic acid as an antioxidant, which Vanderheyden suggests is generally required for therapeutic radionuclide compositions. Accordingly, we find that Yoshinaga is reasonably pertinent to the matter at hand.

In addition, we recognize Appellants' contentions regarding the synergistic antioxidant effect Yoshinaga reports on the combination of ascorbic acid and gallic acid. In this regard, we note that while Appellants' claims comprise a stabilizing amount of a compound of formula (I), which may be gallic acid, and specifically exclude ascorbic acid from the scope of formula (I), Appellants' claim 19 is open to include ascorbic acid as a component other than formula I. Accordingly, Appellants' claimed composition does not exclude an effective stabilizing amount of gallic acid in addition to the presence of a synergistically effective amount of ascorbic acid as suggested by Yoshinaga (*Cf.* App. Br. 16).

We are also not persuaded by Appellants' contention that Yoshinaga fails to suggest "the desirability of using gallic acid with radionuclides" (App. Br. 22). As discussed above, Vanderheyden suggests that antioxidants are generally required for therapeutic radionuclide compositions. Yoshinaga suggests an antioxidant suitable for human consumption. There is no evidence of record to suggest that a person of ordinary skill in this art at the time the application was made would have considered Yoshinaga's antioxidant unsuitable to stabilize therapeutic radionuclide compositions.

In sum, we find no error in the Examiner's *prima facie* case of obviousness.

CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness.

The rejection of claim 19 under 35 U.S.C. § 103(a) as unpatentable over the combination of Sworin, Vanderheyden, and Yoshinaga is affirmed. Claims 20-22, 30, 31, 33, and 35-39 fall together with claim 19.

The rejection of claim 19 under 35 U.S.C. § 103(a) as unpatentable over the combination of Toner, Vanderheyden, and Yoshinaga is affirmed. Claims 20-22, 30-33, and 35-39 fall together with claim 19.

Obviousness-type Double Patenting:

While Appellants separately identify the requirements of each dependent claim on appeal, Appellants contend that for each dependent claim on appeal “[t]he Examiner has failed to make a proper *prima facie* showing for these claims for the reasons above” regarding independent claim 19 (App. Br. 10-14). We do not find Appellants’ separate listing of the dependent claims on appeal to represent a separate argument of these claims. Accordingly, the dependent claims included in each ground of rejection will stand or fall together with independent claim 19.

ISSUE

Does the preponderance of evidence on this record support the Examiner’s rejection of the claimed subject matter under the judicially created doctrine of obviousness-type double patenting?

FINDINGS OF FACT

FF 7. Appellants do not dispute that Rajopadhye teaches a pharmaceutical composition and kit comprising a radionuclide within the scope of Appellants’ claimed invention (Ans. 7).

FF 8. The Examiner finds that Rajopadhye fails to teach the use of stabilizers in the composition or kit (*id.*).

FF 9. The Examiner relies on Vanderheyden and Yoshinaga as discussed above (FF 3-6).

ANALYSIS

Appellants contend that Rajopadhye, like Sworin and Toner above, fails to teach a composition comprising compounds of Formula I and Vanderheyden and Yoshinaga fail to make up for this deficiency in Rajopadhye for essentially the same reasoning discussed above (*see* App. Br. 7-10). We are not persuaded for the reasons set forth above.

CONCLUSION OF LAW

The preponderance of evidence on this record supports the Examiner's rejection of the claimed subject matter under the judicially created doctrine of obviousness-type double patenting.

The rejection of claim 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22 and 28-30 of Rajopadhye in view of Vanderheyden and Yoshinaga is affirmed. Claims 20-22, 30-33, and 35-39 fall together with claim 19.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

alw

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